REMARKS

After entry of this amendment, claims 10-14, 16, 20-22, 24, 33, 34, 37-40, 42, and 47 are pending. Claims 1-9, 14, 15, 17-19, 23, 25-32, 35-36, and 41-46 are cancelled without prejudice or disclaimer. Claims 10, 11, 12, 13, 24, 34, and 37 have been amended to delete non-elected sequences and claims 15, 25-32, and 35-36 have been cancelled without prejudice or disclaimer as being directed to non-elected subject matter. Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. The subject matter of original claims 14 and 42 has been incorporated into claims 11 and 37, respectively. Accordingly, claims 14 and 42 have been cancelled without disclaimer or prejudice. The amendments to claim 10 find further support, for example, in original claims 1, 9, and 14, and in the specification at page 19, paragraph [047] and at pages 20-21, paragraph [049]. The amendments to claims 11, 21, 22, 24, and 37 find further support, for example, in original claims 14 and 42, and in the specification at page 19, paragraph [047], and/or at pages 20-21, paragraph [049]. New claim 47 finds support in the specification at pages 20-21, paragraph [049]. No new matter has been added.

Please note that the page and paragraph numbers referred to in this response correspond to those of the International Published Application WO 2004/013304, which is the specification submitted in the initial filing under 35 U.S.C. § 371 of this national stage application.

Objections To The Specification and the Claims

The Examiner objected to the specification for containing an embedded hyperlink. In light of the amendment to the specification, the objection is believed to be rendered moot. Withdrawal of the objection is respectfully requested.

The Examiner objected to claims 1-3, 11-13, 24, 34, and 37 as being drawn to non-elected sequence embodiments. The claims have been cancelled or amended without disclaimer or prejudice to delete the non-elected sequences. In light of the amendments, the objection is believed to be rendered moot. Withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 21, 22, and 24 for allegedly being indefinite. Specifically the Examiner rejects claim 21 for the term "first," claims 21 and 22 for the "complement," and claim 24 for allegedly omitting steps, for the "complement," requesting that activity and the conditions for stringency be added. Applicants believe that the Examiner's concerns have been addressed by the amendments. In light of the amendments, reconsideration and withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3, 6-14, 16, 20-22, 24, 33-34, 37-40 and 42 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure. Claims 1-9 have been cancelled without prejudice or disclaimer and as such the rejection as to these claims is rendered moot. Applicants respectfully traverse the rejection.

The Examiner contends that complementary sequences and sequences that hybridize are not enabled for modulating a seed storage compound because these allegedly are only used as antisense sequences to inhibit expression of some compound (Office Action, page 6 last sentence through 7, line 2). The Examiner also alleges that "guidance is not sufficient to allow one to make and use antisense expression of sequences 70% identical to SEQ ID NO: 23" (Office Action, page 7, lines 12-14). Applicants disagree. Contrary to the Examiner's assertion, the claims do not recite antisense expression of sequences 70% identical to SEQ ID NO: 23. Rather the former claims recited the complement to the full-length LMP nucleic acid of a) or b), *i.e.* SEQ ID NO: 23 or a polynucleotide encoding the polypeptide of SEQ ID NO: 24. Nevertheless, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer. The claims do not recite complements or antisense and as such the rejections based on complements and antisense are believed to be rendered moot.

The Examiner further asserts that "[e]ffective sequences can not be predicted and must be identified experimentally and tested experimentally." However, the standard for determining enablement is not whether experimentation is needed but rather whether the experimentation would be undue. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001,

1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)) (The enablement requirement of 35 U.S.C. or § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation."). The amount of experimentation can be substantial so long as routine. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine").

The specification provides numerous sequences which affect lipid metabolism, detailed guidance on how to obtain these sequences (see Examples 1-6), on how to identify the sequences (see Examples 7-9), on organism transformation using these sequences (see Examples 10-12), and how to test for functional activity (see Examples 13, 14 and 16). Additionally the specification provides working examples showing activity (see Example 15).

The specification also teaches in detail how to obtain and make variants of the sequences (for example at page 16 paragraph [040], pages 20-22 paragraphs [049]-[051], and page 35 [088]), how to obtain variants from libraries (for example at page 37, paragraphs [092]-[094]), polymorphisms and orthologs (at pages 18-19 [046]-[047]), homologous sequences and biologically active portions *i.e.* domains that participate in metabolism (at page 17 paragraph [042]), which techniques are also known to one of skill in the art as evidenced by the numerous references provided in the specification. Further Example 6 shows how to obtain homologs, heterologous genes and orthologs by homology and hybridization (see paragraphs [0135]-[0137]). Specific positions of functional domains are also provided such as in Table 4 (for SEQ ID NO: 23 see page 13 and page 14 paragraph [035]).

Selection of sequences and variants and calculation of homology using relevant software are also described in detail in Example 9, paragraphs [0145]-[0147], and at page 21 paragraph [050].

Furthermore, in view of Examples 13-16, one skilled in the art would recognize that screening and testing for lipid metabolism activity and digalactosyldiacylglycerolsynthase (hereinafter "DGD") activity in microorganisms and plant species is routine and is not undue experimentation. The same applies to screening and testing the lipid metabolism activity and

DGD activity of homologs or variants of the sequences as claimed in the present application, which techniques are also known to one of skill in the art as evidenced by the numerous references cited in the specification and the Examples and as demonstrated in WO 06/053743. It is submitted that determining the functional activity is routine experimentation and not undue experimentation. Compare, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). The test for whether experimentation is "undue" is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). In the present case, the specification provides detailed guidance and teaches in the Examples the types of routine screening and assays which are employed to confirm the claimed activity and additionally working examples showing activity.

Additionally, using the sequences of the present application and following the detailed guidance of the present specification, DGD homologs in other plants, such as *Brassica napus*, have been subsequently isolated *via* hybridization and/or PCR amplification. See WO 06/053743 also published as co-pending U.S. Publication No. 2008/0127369. The DGD sequences from *Brassica napus* described in U.S. Publication No. 2008/0127369 are approximately 88% identical to the present sequences at the nucleic acid level and approximately 87% at the amino acid level. Further these DGD *Brassica napus* homologs were found to have similar expression activity as the present sequences, which activity was shown through routine assays as described in the present application. Thus the specification clearly provides the guidance necessary for one skilled in the art to make and use the full scope of the invention.

The Examiner cites to Bartoszewski *et al.* (hereinafter "Bartoszewski") for allegedly teaching that transgenic plants were not obtained after attempts to transform more than 1400 explants with either sense or antisense constructs which were 75% identical to the target gene. The Examiner asserts that the 75% identity as opposed to the 70% claimed is not dispositive. Applicants agree that the amount of percent identity is not dispositive but disagree on the applicability and characterization of Bartoszewski. Bartoszewski teaches isolation and cloning

of a very specific gene, *i.e.* the tomato cytochrome P450 *CYP72A2* gene. The success or failure of Bartoszewski to produce transgenic plants using this particular wound inducible gene has no relevance to the claimed sequences of the present invention which relate to totally different genes and metabolic pathways. The Examiner further cites to Stein *et al.* (hereinafter "Stein") for allegedly teaching that 1 in 8 antisense sequences would be effective in inhibiting expression. Applicants fail to see the relevancy of Stein which relates to drug development and to phosphorothioates as the major antisense oligonucleotide in human clinical trials. Stein does not teach or suggest anything relating to microorganism or plant lipid metabolism or to any of the sequences claimed. Contrary to the Examiner's assertions, as explained above, following the teaching of the present application, DGD homologs from other plant species have been isolated and were shown to have similar expression activity through routine assays.

The Examiner also alleges that sequence homology, such as percent identity or gene identification via hybridization, is not sufficient to predict or determine functionality of a coding sequence because computer analysis of genome sequences is flawed, citing to Doerks *et al.* and Truska *et al.* for alleged unpredictability. Applicants respectfully disagree.

The analysis in Doerks relates to assigning functional annotations to uncharacterized protein families (UPFs) that contain "putative, poorly annotated proteins that are usually labeled as 'hypothetical'." (Doerks, page 248, column 1, second paragraph, lines 2-5). These uncharacterized protein families differ from protein families such as the lipid metabolism enzymes which have been cloned and functionally characterized in several different species. Even though Doerks selected uncharacterized protein families that were especially difficult to characterize, Doerks nevertheless discloses successful assignment of function to more than 700 of about 1300 proteins analyzed which were clustered in 25 of the 58 distinct UPFs by relating to proteins with annotated functional features. (See Doerks, page 250, first column, first full paragraph, lines 1-4, and page 248, right column, second paragraph, last sentence). Furthermore, in the Doerks study, homologs were selected by PSI-BLAST based on an expected ratio of false positives (E=0.001) (see Doerks, page 248, middle column, third paragraph) and not by any specific level of sequence homology. The Examiner argues that Doerks states that the highest scoring database protein does not necessarily share the same functions (see Office Action page 4, citing to Doerks at page 248, first column, first paragraph, lines 20-23). However, the "highest

scoring" protein in Doerks does not relate to a specific sequence homology and may actually share very little homology with the sequence of interest in contrast to the sequences of the present invention which share at least 70% (or 80%) homology. Doerks further discloses that when reasonable predictions could be made, the iterations were not continued. (see Doerks, page 248, left column, lines 10-13). In contrast to the Examiner's conclusion, Doerks assigned and predicted function based on sequence comparisons to proteins with annotated functional features. (see Doerks, page 248, left column, lines 21-23). Thus, because Doerks does not show comparisons with specific sequence homology (in contrast to the sequences of the present invention which share at least 70% (or 80%) homology) and because the comparisons in Doerks relate to a limited subset of sequences (*i.e.* uncharacterized protein families), Doerks is not applicable to support the Examiner's generalized conclusions.

The Examiner contends that Truska only suggests that the described cDNAs were conlinin cDNAs referring to pages 144-145. Applicants disagree with this characterization. Rather Truska teaches at pages 144-145:

> "[b]ut up to now, these proteins have not been characterized at the molecular level. We applied differential screening of the embryo specific cDNA library and **cloned the conlinin gene**. The abundance of isolated clones in the cDNA library, the high level and seed specifity of the expression and temporal pattern of the transcription, as well as the presence of a signal peptide, conserved glutamine-rich stretches and cysteine residues, and the overall amino acid composition **strongly** suggest that the cDNAs and their genomic counterparts **indeed encode conlinin**." (Truska at page 144-145).

Further contrary to the Examiner assertion, Truska states "we **describe the identification of two flax conlinin cDNAs** *cnl1* and *cnl2*" (page 142, left column, lines 5-6) and "two clones (*cnl1* and *cnl2*) from the first group were **fully sequenced and studied**." (page 142, right column, lines 5-6).

The Examiner then concludes that putative structural genes isolated by hybridization and which hybridize or which are complementary are not enabled and it would allegedly require undue experimentation to determine which hybridizing sequences were structural genes. Applicants strongly disagree with this conclusion or that Truska supports such a conclusion. Contrary to the Examiner's assertion, Truska teaches the isolation and identification of two flax conlinin cDNAs *cnl1* and *cnl2* and their genomic sequences, which were isolated *via* hybridization and/or PCR amplification (see Truska, page 142, left column, lines 5-6; and

methods at pages 145-146, sections 4.3-4.6). Furthermore, the present specification provides detailed guidance in Examples 3-9 on obtaining sequences through hybridization and/or PCR amplification which also relates to hybridization of shorter oligonucleotides. Further isolation through hybridization has been demonstrated in co-pending U.S. Publication No. 2008/0127369, as explained above.

Whether or not experimental trial and error would be required to determine if the hybridizable sequences were structural genes or to eliminate inoperable embodiments is not relevant inquiry in determining enablement. Further even if we were to assume that the amount of experimentation to practice the full scope of the claimed invention might be extensive, such experimentation would have been routine. The specification provides detailed screening and assays to determine activity of the sequences and also provides working examples showing activity as explained herein. Furthermore sequencing genes is clearly routine and become highly automated. The methods for performing such screening were also well known to those skilled in the art. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative ... if it is merely routine"). Thus, as shown by the references cited by the Examiner and the detailed guidance provided in the specification any such experimentation is merely routine to one skilled in the art.

Analogous to the finding of enablement by the Board of Patent Appeals and Interferences in *Ex parte Sims* (Appeal No. 1999-1430, Application No. 08/441,893, see attached copy for Examiner's convenience) relating to hybridization claims, the Examiner appears to be unduly concerned that the claims include inoperative species. As set forth in *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances ...." *In re Dinh-Nguyen*, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, *In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *In re Anderson*, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

As in *Ex parte Sims*, the Examiner has not provided any evidence to demonstrate that one skilled in the art would be forced to experiment unduly in order to practice the claimed invention. Any experimentation required would be routine as evidenced by the detailed guidance provided in the specification, by the references cited in the specification, and by even by the references cited by the Examiner. Furthermore, by following the guidance in the present application, one of skill in the art isolated and identified homologs of the present sequences from other plants species, and demonstrated similar expression activity, further supporting the routine nature of the experimentation. Thus, the detailed guidance provided in the present specification and the routine nature of the screening for the claimed activity overcome the unpredictability alleged by the Examiner.

Moreover, regarding the percent identity, the facts are analogous to *Ex parte Sun* (pages 14-16, see attached copy for Examiner's convenience), where the Board of Patent Appeals and Interferences found enablement of a polynucleotide having 80% identity to the coding region of the sequence at issue, when the specification described the chemical structures of a specific polynucleotide and polypeptide it encoded, provided an example of how to screen for activity, indicated important areas of the gene that were conserved and those that could be altered, outlined methods for transfection and transformation of plants, and provided examples of successful expression and transformation. *Ex parte Sun*, Appeal No. 2003-1993, Paper No. 27 (Board of Patent Appeals and Interferences) (See attached copy). Similarly here, the specification has described specific polynucleotide sequences and polypeptides they encoded (claimed sequences SEQ ID NO: 23 and 24), provided examples of how to screen for activity (see Examples 13-16), provided functional protein domains (see Table 4 and page 14 paragraph [035]), provided details on transfection and transformation (Examples 10-12), and provided working examples of successful expression and transformation (Examples 13-16). Furthermore, the Examiner acknowledged that the amount of the percent identity is not dispositive. Thus, it is well within the level of ordinary skill in the art to prepare the nucleic acid sequences as claimed. Moreover, the specification further teaches in detail how to make variants; calculate the percent identity between the disclosed sequences and variant sequences; and test the variant sequences to determine the claimed activity. Thus, only routine experimentation would be required to practice the claimed invention.

In light of the comments above, Applicants' attorney respectfully reminds the Examiner that the representations in the specification as to the manner of making and using the claimed invention must be taken as in compliance with the first paragraph of 35 U.S.C. §112, unless there is objective evidence or scientifically based reasoning inconsistent with the specification. *See In re Marzocchii and Horton*, 169 U.S.P.Q. 367 (C.C.P.A. 1971). "It is the Patent Office's burden to present evidence that there is some reason to dispute the enablement provided in the specification. Unsupported speculation or conjecture on that the invention "might not work" will not support a rejection based on 35 U.S.C. §112, first paragraph." *Id.*

As provided herein, Applicant respectfully submits that the art and the specification provide ample guidance and predictability for the present claims and the Examiner has not presented the evidence necessary to dispute the enablement provided in the instant specification. Accordingly, the Patent Office has not met its burden and reconsideration and withdrawal of the enablement rejections is requested.

Rejections under 35 U.S.C. § 102

Claim 1-3 and 6-9 were rejected under 35 U.S.C. § 102(e) as anticipated by Levin *et al.* (WO 2003/008440; hereinafter "Levin"). Applicants respectfully disagree; however, in order to expedite prosecution, claims 1-9 are cancelled without prejudice or disclaimer. Accordingly, the rejection is moot. Withdrawal of the rejection is respectfully requested.

Claims 1-3, 6-13, 16, 20-22, 24, and 33-34 are rejected under 35 U.S.C. § 102(b) as anticipated by Dormann *et al.* (hereinafter "Dormann"). Claims 1-9 have been cancelled without prejudice or disclaimer and as such the rejection as to these claims is rendered moot.

Applicants respectfully disagree and traverse the rejection. However, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice. The subject matter of claim 14 has been incorporated into claims 10, 11, and 24, and thus also into the claims dependent therefrom. Since claim 14 was not included in the rejection and the subject matter of claim 14 is incorporated into the claims as amended, this rejection is believed to be rendered moot. Because Dormann does not teach every limitation of the claims, Dormann does not anticipate the claims as amended. See *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir.

1997) ("[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference.").

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-3, 6-14, 16, 20-22, 24, 33-34, 37-40, and 42 are rejected under 35 U.S.C. § 103(a) as being obvious over Levin or Dormann in view of Goodman. Applicants respectfully traverse. Claims 1-9, 14, and 42 have been cancelled without prejudice or disclaimer and as such the rejection as to these claims is rendered moot.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner acknowledges that neither Levin nor Dormann teach monocots or modified or increased level of a seed storage compound compared to the wild type variety of the plant. The Examiner relies on Goodman for teaching expression of heterologous proteins in monocots and dicots, alleging that because Goodman does not teach complementation, expression of SEQ ID NO: 23 would result in modified and increased level of seed storage compound in a transgenic plant. Applicants respectfully disagree with the Examiner's characterization of the references.

Levin relates to using sequences as targets for new herbicides. Levin does not relate to expression cassettes or methods related to increasing the level of a seed storage compound in a plant. Dormann discloses isolation of a DGD 1 gene encoding a galactosyltransferase-like protein. Dormann also provides insight into the assembly of the thylakoid lipid matrix and subcellular lipid trafficking in *Arabidopsis thaliana* (Dormann, abstract). Dormann does not disclose that expression of the DGD 1 gene would result in an increased level of seed storage compound in a plant. Goodman relates to transforming mammalians proteins into plants, expression of physiologically active mammalian peptides, and a method for producing interferon in plants. Goodman does not remedy the lack of teaching of Dormann. As with Levin and

Dormann, Goodman does not teach or suggest DGD genes or any plant sequences for use in transformation of a plant which when expressed would result in an increased level of seed storage compound in a plant. Because none of the references cited by the Examiner teach or suggest all the limitations of the claimed invention, a *prima facie* case of obviousness has not been established.

The Examiner concludes by alleging that it would be obvious to substitute the heterologous protein of Goodman with the lipid metabolism protein of Levin or Dormann and express DGD in plants for the purpose of investigating galactolipid biosynthesis and cellular trafficking as taught by Dormann. Applicants strongly disagree with the Examiner's conclusion. This alleged motivation lacks specificity to support a legal conclusion of obviousness. See *KSR*, 127 S. Ct. at 1741 (holding that "there must be some articulated reasoning with some rational underpinning to support a legal conclusion of obviousness."). *KSR* still requires some reason one would have combined Dormann and Goodman and some reason for the substitution a ***mammalian protein*** such as interferon with ***a lipid metabolism plant protein***. *Id.* (holding that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements ***in the way the claimed new invention does***.") (emphasis added). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See MPEP § 2143.01 IV. Simply stating that the proteins can be substituted does not provide a reason that would have prompted a person of ordinary skill in the relevant field to substitute a ***mammalian structural gene*** used for production of physiological active mammalian proteins such as interferon for a ***plant DGD gene*** which expression results in increased level of seed storage compound in a plant. The Examiner has not provided any explanation, rationale, or suggestion in the references cited for why it would be obvious to substitute these genes or how it would arrive at the same result or how it arrives at the claimed invention. Such a statement lacks

the specificity required to support a legal conclusion of obviousness and is thus insufficient to establish *prima facie* obviousness.

Further, it is well established that under 35 U.S.C. § 103 the Examiner must consider the reference in its entirety, *i.e.* as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); see also *KSR*, 127 S. Ct. at 1740, MPEP § 2141.03 (VI). It is improper to combine references where the references teach away from their combination. *See* MPEP § 2145 (X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). In addition, the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements ***in the way the claimed new invention does***." See *KSR International Co. v. Teleflex Inc.*, 1741 82 USPQ2d 1385, 1396 (2007) (emphasis added). Thus, it is impermissible to simply engage in a hindsight reconstruction of the claimed invention where the reference itself provides no teaching as to why the applicant's combination would have been obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

Dormann discloses that there are two DGD genes in *Arabidopsis* and that "[i]n the absence of DGD1, monogalactosyl lipid cannot be synthesized via the ER-pathway but the plastid pathway can compensate for this deficiency." (Dormann, p. 2182, end of middle column to top of right column). Dormann thus discloses that there is strong regulation of the two galactosyl lipid biosynthesis pathways. Further, Dormann discloses that "[e]xpression of DGD1 alone did not lead to digalactosyl lipid biosynthesis." (Dormann, p. 2183, right column, second paragraph). Thus from the teaching of Dormann, one of skill in the art would not have been prompted to overexpress DGD 1 alone to result in an increased level of seed storage compound

in a plant as in the present application without hindsight reconstruction. Thus Dormann teaches away from using the DGD gene alone for increasing the level of a seed storage compound.

As mentioned above, Dormann discloses ***plant DGD genes***, in contrast to Goodman which describes using ***mammalian genes*** for producing physiologically active proteins such as interferon. Because Dormann and Goodman disclose totally different genes from different sources and involved in totally different pathways, Dormann and Goodman are not combinable. Even assuming *arguendo* that they were combinable, there is no teaching or suggestion for the desirability to express DGD for increasing the level of seed storage compound in a plant or that mammalian genes for production of physiologically active proteins like interferon are substitutable for plant DGD genes for increasing the level of seed storage compound in a plant. Thus, Levin or Dormann and Goodman do not render the claims obvious for these additional reasons.

Moreover, a reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. *See* MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). Assuming *arguendo* Dormann and Goodman were combinable, there would be no expectation of success since Dormann teaches that DGD alone does not lead to lipid synthesis and the Examiner has further not provided any basis for the substitution of a ***plant DGD gene*** in a ***mammalian gene construct***.

For at least these reasons, Levin, Dormann and Goodman, alone or in combination, do not render obvious the subject matter of the independent claims or the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a two-month extension of time to and including December 23, 2008 with the required fee authorization. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00379-US from which the undersigned is authorized to draw.

Respectfully submitted,

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